## REMARKS

Claims 1-27 are currently pending. Claim 1 has been amended herein. Support for the amendments can be found at least at page 4, lines 15-20 of the specification. No new matter has been presented.

Applicants would like to draw the Examiner's attention to the following co-owned application, which discloses and claims related subject matter, U.S.S.N 10/507,345 filed on March 24, 2005.

### Examiner Interview

Applicants thank Examiner for interview of February 6, 2009 regarding potential claim amendments for the claims of the instant Application as well as the art rejections.

### 35 U.S.C. § 112, first paragraph Rejections Overcome

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically the Examiner states that claim 1 recites a tablet, "...completely covered by a film..." however, this limitation allegedly contradicts the description of the tablet in the specification. (*See*, Office Action at page 3). Applicants traverse this rejection with respect to the claim as amended herein.

Applicants have amended claim to no longer recite the phrase "completely covered by a film," rather, claim 1 is directed towards "a tablet being coated by a film of polymeric material." Claim 1 has been amended to recite that the "film coating produced by completely coating the therapeutic tablet system with the polymeric material and generating one or more laser incisions delimiting an area of the polymeric material of a geometric shape." Applicants submit that claim 1, as amended herein, recites the steps of how the tablet coating is produced, *i.e.* completely coating the tablet system with the polymeric material and then generating the laser incisions that delimit a predetermined area. (*See*, Specification at page 4, lines 16-19). Thus claim 1 does not contradict the specification.

Applicants respectfully request that this rejection be withdrawn.

### 35 U.S.C. § 102 Rejections Overcome

Claims 1, 2, 4, 5 and 8-25 remain rejected under 35 U.S.C. §102(b) as allegedly being anticipated by US 5,487,901 and 5,650,169 ("Conte"). Applicants disagree.

In order to anticipate a claim, a reference must teach each and every element of the claim. (*See*, MPEP §2131). Specifically, the Examiner alleges that Conte discloses a pharmaceutical tablet composed of an upper layer containing an active ingredient, formulated for immediate release, an intermediate layer that does not contain any active agents and is formulated with polymers as a semipermeable membrane, and a lower layer of the same formulation as the upper layer containing identical or different active agents and being *almost* completely coated with an insoluble polymeric coating (*emphasis added*). (*See*, Office Action at page 3). The Examiner asserts that the method by which the tablet of claims 1, 2, 4, 5 and 8-25 is made is different from the method described in Conte but that the process by which the claimed product is made will only hold patentable weight if the process imparts functional or structural limitations to the product that would distinguish it from the product of Conte. (*See*, Office Action at pages 4-5). Applicants traverse the rejection with respect to the claims as amended herein.

Applicants have amended claim 1, from which the remaining claims either directly or indirectly depend, to recite that the tablet is coated by a film of polymeric material insoluble in aqueous fluids to form a film coating, said film coating produced by completely coating the therapeutic tablet system with the polymeric material and generating one or more laser incisions delimiting an area of the polymeric material of a geometric shape and predetermined dimensions. Applicants submit that the process by which the therapeutic tablet system described in claims 1, 2, 4, 5 and 8-25 is made imparts functional and structural limitations to the claimed product that distinguish it from the product of Conte. Applicants submit that the process of making the therapeutic tablet system of claims 1, 2, 4, 5 and 8-25 causes structural differences between this system and the tablets taught in Conte, that give the therapeutic tablet system of claims 1, 2, 4, 5 and 8-25 greater stability and a more advantageous release profile for constant steady release of the drug.

Applicants submit that the process of making the therapeutic tablet system of claims 1, 2, 4, 5 and 8-25 gives the system of claims 1, 2, 4, 5 and 8-25 greater stability than the tablets taught in Conte. Applicants submit that the incision(s) delimited film coating of the tablet of claims 1, 2, 4, 5 and 8-25 remains intact before contact with aqueous fluids. As articulated above, the laser beam etches an incision in the film polymeric coating and delimits an area of geometrical shape and of predetermined dimensions, the incision notches the film coating without interfering with the underlying tablet. (*See*, Specification at page 6, lines 3-10). The

area delimited by the laser incision is not removed until contact with an aqueous fluid. (*See*, Specification at page 6, lines 10-14).

Whereas the tablet in Conte does not provide any such protection of the active ingredients as the raised tops of the tablets are removed with an abrading system which scrapes out the raised tops leaving the active ingredient of the entire area exposed. (*See*, Conte at Column 6, lines 1-4). Applicants submit that the tablet of the claimed invention is different than the tablet in Conte, as Conte does not provide a method to stabilize the active ingredient exposed by the abrading process. (*See*, Specification at page 6, lines 24-27 and Declaration under 37 C.F.R. § 1.132 of Ubaldo Conte submitted on March 10, 2008).

Applicants submit that the process for making the therapeutic tablet system described in claims 1, 2, 4, 5 and 8-25 imparts functional or structural limitations to the product that distinguish it from the product of Conte. Thus, Conte cannot anticipate claims 1, 2, 4, 5 and 8-25. Reconsideration and withdrawal of this rejection is requested.

Claims 1, 3 and 6-27 remain rejected under 35 U.S.C. §102(e) as allegedly being anticipated by US 6,599,284 ("Faour"). Applicants disagree. As stated above, in order to anticipate a claim, a reference must teach each and every element of the claim. (*See*, MPEP §2131). The Examiner indicates that Faour discloses a controlled release osmotic device comprised of an outer layer or external coating containing active ingredients, an intermediate layer forming a semipermeable membrane and an inner layer or core containing active ingredient, and the dosage form comprises a passageway formed by a laser incision. (*See*, Office Action at pages 5-6). Applicants traverse this rejection with respect to the claims as amended herein.

Specifically, as articulated above, Applicants have amended claim 1, from which the remaining claims either directly or indirectly depend, to recite that the tablet is coated by a film of polymeric material insoluble in aqueous fluids to form a film coating, said film coating produced by completely coating the therapeutic tablet system with the polymeric material and generating one or more laser incisions delimiting an area of the polymeric material of a geometric shape and predetermined dimensions. In contrast, Faour teaches an embodiment of an osmotic device that comprises a core containing an active agent, an osmopolymer, as osmagent and at least one excipient; and the core is surrounded by a *semipermeable membrane* that has a passageway that delivers the active agent to an environment of use in a controlled manner. (*See*, Faour at column 8, lines 16-24 and Figure 4). The passageway described in Faour can be

formed by controlled laser perforation. (*See* Faour at column 13, lines 48-50.) The laser in Faour does not generate one or more laser incisions delimiting an area of the polymeric material of a geometric shape and predetermined dimensions. The laser in Faour creates a passageway like that made by a drill. Again, Applicants submit that Faour does not teach or suggest utilizing coatings that are impermeable to aqueous fluids as required herein.

Applicants submit that Faour does not teach each and every limitation of claims 1, 3 and 6-27 and thus cannot anticipate them. Reconsideration and withdrawal is requested.

## Conclusion

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Should any questions arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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